

EXAMPLE _ NOT FOR USE
PARTICIPANT INFORMATION SHEET
NIHR BIORESOURCE
V x.x Date: xx/xx/xxxx

In England around 30% of the population are said to be living with a long term health condition such as diabetes, heart disease or mental health conditions. Living with a chronic disease has a major impact on a person's quality of life and on their family. The BioResource, has been set up to help research health and medical conditions. We would like to invite you to join the NIHR BioResource. Please take the time to read the following information carefully and feel free to ask us if there is anything that is not clear or if you would simply like more information.

What is the purpose of the NIHR BioResource?

The NIHR BioResource comprises of a number of local BioResources around the country and consists of a panel of thousands of volunteers who are willing to help with research. The NIHR BioResource National Coordinating Centre Headquarters is based in Cambridge. Volunteers joining the panel will be asked to donate a small blood or saliva sample and give consent to be invited to participate in medical research studies on the basis of data gathered from samples and information they have supplied. Information and samples from this resource may also be made available to other scientists working in biomedical and healthcare research.

The NIHR BioResource is supporting studies looking at how genes and other factors influence disease. By gaining more information on the genes involved in disease we can begin to identify better treatments to reduce the effect of the disease or even cure it. A more complete understanding may enable researchers to prevent some diseases occurring altogether in the future.

TAKING PART

Who can join the NIHR BioResource?

The NIHR BioResource is recruiting volunteers with and without health conditions. By joining, you will be helping researchers investigate and understand why some individuals have a disease.

Do I have to join the NIHR BioResource?

It is completely up to you to decide whether or not you wish to join. If you decide not to join your decision will not affect the healthcare you receive in any way. If you wish/agree to join, you will be free to withdraw at any time and without having to give a reason.

What will happen if I agree to join the NIHR BioResource?

- read and sign a consent form.
- provide your name, date of birth, NHS number and contact details (including email and mobile phone if available) and allow us to store them.
- donate a small sample of blood (3-4 teaspoons) or saliva.
- complete a questionnaire about your health and lifestyle (online or paper).

- allow us to collect, store and analyse health information about you (including accessing your medical or other health-related records, (for example through NHS Digital).
- in the future you may be invited to provide a further small sample of blood, or further samples, if the initial sample you provided was insufficient for certain types of testing. DNA will be isolated from their sample and will be used to determine their genetic make-up.
- Agree to be contacted in the future to be involved in other research studies. We will use your blood/saliva sample, and additional information, to match you to research studies that are looking for volunteers. You can decide whether or not to be involved at the time, and are under no obligation to do so.

SAMPLES

What will happen to the samples I give?

We want to know how genes influence disease. Genes are made up of DNA. We will isolate, analyse and store a sample of your DNA from your donated blood or saliva sample and, using advanced laboratory techniques available now or to be developed in the future, we will determine your genetic makeup. This may include determining the sequence of all or part of your DNA code. We may also isolate and test other components of your blood such as cells, RNA, protein and metabolites. Researchers may seek access to your samples and related data, but your personal details will never be released to researchers without your knowledge. Your samples will be kept in a secure location.

DATA AND COMMUNICATION

What will happen to any data produced from the samples I give?

Anonymous data about you may be stored in an electronic archive and made available to researchers. This data may include part of or your entire DNA code. It also may include the results of other tests performed with your samples and other information from the research database that does not identify you personally, e.g. your age in years, your gender.

Researchers will have to make a request to access this data and explain how they will use it, e.g. which research question they are trying to answer. This type of system is referred to as 'managed access'. Genuine researchers will be given access to the data for their research, and they will be reminded of their obligation to keep your data safe by accepting the terms of a data transfer/access agreement.

'Managed access' requests could come from researchers who are working in the public and charitable sector (Universities, Research Institutes) or in commercial companies, either in the UK or overseas.

Researchers share the results of their studies by means of reports or publications, which includes placing information/data on the internet, in press articles, in project leaflets and through other media. Under no circumstances will information that identifies you personally be disclosed in any of these documents.

Will my details be kept confidential?

Yes. Best ethical and legal practice will be followed to ensure that all information collected about you will be handled in confidence. Your samples will be labelled with a unique sample study number before being transferred to the laboratory for testing and information from genetic and other tests will be stored separately from your personal details. Access to your personal details will only be available to necessary members of NIHR BioResource staff, and IT staff that manage our database. Information from these tests will not be used or made available for any purpose other than for research. You will not be identified personally in any report or publication.

Transparency Statement under General Data Protection Regulation (GDPR)

The Cambridge University Hospitals NHS Foundation Trust is responsible for managing the NIHR BioResource - Research Tissue Bank based in the United Kingdom. We will be using information from you and your medical records in order to undertake this study (NIHR BioResource – Research Tissue Bank) and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Cambridge University Hospitals NHS Foundation Trust will keep identifiable information about you for 10 years after the study has finished (to March 2032 in the first instance), and we may approach you to extend this.

Your rights to access, change or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally-identifiable information possible.

You can find out more about how we use your information at URL: <https://bioresource.nihr.ac.uk> or by contacting: nbr@bioresource.nihr.ac.uk

The NHS site [xxxxxxxxxxxx] will collect information from you and your medical records for this research study in accordance with our instructions.

Your local NIHR BioResource Centre (at NHS or other site) will use your name, NHS number and contact details including address, phone number and email address (where available) to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study. Individuals from the NIHR BioResource (which is managed by the Cambridge University Hospitals NHS Foundation Trust) and regulatory organisations may look at your medical and research records to check the accuracy of the research study. The local NHS/other site will pass these details to NIHR BioResource along with the information collected from you and/or your medical records.

The only people in NIHR BioResource who will have access to information that identifies you will be people who need to contact you to send newsletters, invite you to events such as open days, or invite you to further studies, or audit the data collection process. The people who analyse the information will be told not to attempt to identify you and will not be given your name, NHS number or contact details.

The NIHR BioResource will collect information about you for research from medical records, health registries and sometimes we will ask you to complete questionnaires. This information will include

your name, NHS number, contact details and health information, which is regarded as a special category of information. We will use this information to try to elucidate the causes of common and rare disease, and generate faster ways to diagnose patients.

Your information could be used for research in any aspect of health or care, and could be combined with information about from other sources held by researchers, the NHS or government.

Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you can be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Invitation to future studies

The BioResource supports many different research studies. We may, on the basis of the data held in the research database, contact you to ask whether you would like to take part. You will be provided with information regarding each of these studies and will be free to decide whether or not to participate.

Some research will not require any further input from you as the sample, data generated from your sample and information you provided/granted us access when you joined can be used for research purposes.

How often will I be contacted?

We closely monitor the number of times you are approached and invited to future studies. We greatly appreciate the effort made by volunteers and are happy to contribute towards travel/parking costs incurred by volunteers participating in studies.

We may contact you with information about the progress of the BioResource through newsletters or open events but you can choose not to receive such communication if you would prefer.

RISK AND BENEFITS OF JOINING

What are the risks and disadvantages of joining the NIHR BioResource?

Joining the BioResource will involve donating a small sample of your blood or saliva. Qualified, experienced staff will collect the blood sample but blood sampling can cause some discomfort when the needle is placed in the vein and the blood is drawn. There is also a possibility that a small bruise may develop.

What are the benefits of joining the NIHR BioResource?

There will be no direct benefit to you but you will be making a contribution to science and there may be a benefit to the future development of healthcare provision.

RESULTS

Can I know the results obtained from my study samples?

The NIHR BioResource does not intend to undertake analysis of data generated by genotyping or sequencing of DNA samples collected at the time of enrolment to identify variants that may have clinical significance, and hence does not plan to provide feedback of genetic findings. We will notify you if this changes.

Will any of the results obtained with my sample predict the risk of disease?

We cannot answer this question. Many of the studies that will be carried out using these samples aim to discover variations in the genetic code (so called genetic markers) that might predict the risk of certain diseases. However, it may be years before we can confirm how important or accurate these markers are and determine the associated risk.

If you are contacted to take part in a future study, this does not mean that your health is at risk. All individuals carry risk and protective DNA variants in their genes, and we are a long way from understanding how they balance each other and what combination of markers interacting with other factors such as age, gender, smoking and drinking habits, etc. cause disease.

What happens if an invention is made using my sample?

Your donated samples and related information are given as an absolute gift, i.e. without receiving a payment and without conditions. The BioResource is operating on a non-commercial basis, meaning it does not sell your sample to make a profit and will not allow anyone else who is working with the sample to do so either. However, if samples are made available to other research institutions or to commercial companies, a fee may be charged to cover the BioResource operational costs.

In the future, your sample may help researchers in the public and commercial sector to make an invention, for example, develop a new product to diagnose or treat a disease. If an invention results from the research undertaken with your sample, you will not receive any compensation, recognition or payment. BioResource partners in the public sector may work together with commercial companies to develop inventions for the benefit of patient and donor care, and we hope that such products are brought into use to improve healthcare in the future.

WITHDRAWAL PROCESS

What if I no longer want to be a member of the NIHR BioResource?

Volunteers are free to withdraw from the BioResource at any time without giving a reason. If you choose to withdraw:

- You will be asked to specify whether you would like us to destroy the sample(s) you have donated and which are stored at the central archive.
- It will not be possible to destroy samples already prepared or already distributed for testing.
- Your personal information will be retained in an archive so that a record remains of your initial consent and the withdrawal process.

- Should you wish, no further data will be retrieved from your health-related records and no new data from laboratory measurements will be added to the research databases; pre-existing data will not be used in further analysis wherever possible.
- Pre-existing data and data that has already been distributed to other researchers cannot be destroyed.
- Once confirmation of your decision to withdraw is received, you will not be contacted again by the BioResource.
- If the BioResource is unable to confirm your decision, your sample(s) and data will be retained for future use, but you will not be contacted again.

FUNDING & SPONSORSHIP

Who funds and sponsors the NIHR BioResource?

The NIHR BioResource is funded by the National Institute for Health Research (NIHR). The study has been reviewed and approved by East of England - Cambridge Central Research Ethics Committee.

Cambridge University NHS Foundation Trust is the establishment responsible for the management of the NIHR BioResource – Research Tissue Bank.

Further information

If you want more information before deciding or have any queries, please feel free to contact the NIHR Bioresource team on 0800 090 2233 or e-mail us on nbr@bioresource.nihr.ac.uk

Thank you for considering joining the NIHR BioResource.

<https://bioresource.nihr.ac.uk/>